

**Subject: FW: LJ 100 Has Obtained Self Affirmed GRAS Status and Approval from Health Canada**

**Date:** Sunday, October 27, 2013 8:22 PM

**From:** Dr. Steven Forrest <drforrest@forresthealth.com>

**To:** Home home@forresthealth.com

**Subject: LJ 100 Has Obtained Self Affirmed GRAS Status and Approval from Health Canada**

For Immediate Release

LJ100 Has Obtained Self Affirmed GRAS Status And Approval from Health Canada

BRADENTON, FL – Annie Eng, CEO of HP Ingredients, has announced that its signature, science-backed ingredient, LJ100 (tongkat ali; *Eurycoma longifolia*) has obtained not only self-affirmed GRAS status, but an approval from Health Canada.

Under Sec. 201(s) of the FD&C Act [21 U.S.C. 321(s)], a substance is Generally Recognized as Safe (GRAS) if it is generally recognized among experts qualified by training and experience to evaluate its safety either through scientific procedures or common use in food. Self-determination of GRAS status based on a history of safe use in food requires that the substance was commonly used before 1958, and that the safety of the substance is “established by generally available data, including evidence of a substantial history of use of the substance by a considerable number of consumers.

That history of safe use of *Eurycoma longifolia* dates back approximately 4,000 years ago to a notable series of texts from China.

Some aspects of Tongkat Ali’s adaptogenic, health-building qualities are due to testosterone increases and freeing properties. Testosterone has over a hundred benefits to the body and is needed by men and women to maintain proper health. Health studies cited in HP Ingredients extensive scientific review demonstrate the safety of Tongkat Ali -- its effectiveness is known from hundreds of studies done in vitro, lab animals and people.

Explains Eng, "Eurycoma longifolia, or Tongkat Ali, has extensive documentation of ancient traditional use that leads to modern scientific studies and these studies validate its rich tradition of use in human health. Modern sophisticated science and technology have produced specific improvements over traditional preparation methods, leading to products like LJ100®. The result is concentrating Tongkat Ali root into a 100:1 water extract standardized to 40% glyco saponins, 0.8% eurycomanone and 22% eurypeptides. Additionally, careful manufacturing methods ensure a product that is free from contamination – a large, widespread problem with many herbal products. These water extracts of Tongkat Ali are used in many clinical studies and animal studies because they are effective while having a great margin of safety. It is classified under the World Health Organization, Global Harmonization System, Classification of Chemicals, in Category 5 – as having no toxicity. This safety factor is so large that Eurycoma longifolia water extract is very safe for human consumption, under normal conditions of use, whether as an herbal tonic or clinical remedy."

Among the extensive cache of Eurycoma longifolia published research are five most recent (2010-2013):

1. Journal of the International Society of Sports Nutrition, 2013, 10, 28. "Effect of Tongkat Ali on stress hormones and psychological mood state in moderately stressed subjects." Talbot, Talbot, George, Pugh. 63 subjects (32 men, 32 women) with moderate stress taking 200mg of LJ100 or placebo for 4 weeks. LJ100 group showed improved mood state, reduced cortisol exposure (-16%) and increased testosterone status (+37%).
2. Phytotherapy Research, 2013, June, 11. "Tongkat Ali as a Potential Herbal Supplement for Physically Active Male and Female Seniors – A Pilot Study." Henkel, Wang, Bassett et al. 25 physically active elders (13 men, 12 women), taking 400mg of LJ100 for 4 weeks experience increase in total testosterone (15.1% in men, 48.6% in women), increase in free testosterone (61.1% in men, 122% in women), increase in muscular force (16.6% in men), and decrease in SHBG (20.8% in women)
3. Randomized clinical trials on Evidence Based Complimentary and Alternative Medicine (2012): 109 healthy men taking 300mg of Lj100 or placebo for 12 weeks. LJ100 group showed improvement in Quality of Life, Physical and Vitality domain, decrease SHBG, fat mass loss was observed in overweight subjects
4. LJ100 as testosterone booster for managing men with late-onset

hypogonadism on First International Journal of Andrologia (2011): 76 patients taking 200mg of LJ100 for 4 weeks. Patients with % with normal Testosterone Level raise from 35.5% to 90.8%. Mean testosterone improve from 5.66 nm (before study) to 8.31nm (after study), 46% increase in total testosterone level in 30 days

5. LJ100 in Managing Idiopathic Male Infertility on Asian Journal of Andrology (2010): 75 patients taking 200mg of LJ100 for 3 months. Testosterone increase from 5.66nm to 8.31nm. Improve sperm motility and volume, allowing for 14.7% spontaneous pregnancies

The US Patent No. 7,132,117 B2 for HP Ingredients' LJ100® is the source material in many of the reviewed clinical studies, which simply means that LJ100® is the same material used in many scientific studies and will duplicate outcomes and results safely.

Eng concludes, "Our extensive review based on outside expert analysis and experience strongly affirms the long history of use of Eurycoma longifolia Jack in food in widespread populations; and the reasonable certainty of safety for its intended use, thus fully supporting Self-Determination of GRAS for LJ100®, a standardized freeze-dried water extract of Eurycoma longifolia Jack.

In related news, Eng announced that LJ100® has been approved by Health Canada, the government department that oversees regulation of health products and ingredients for sale to Canadian consumers.

### About HP Ingredients

HP Ingredients is a fast growing innovative nutraceutical company focused on bringing science based and patented natural remedies to the nutraceutical industry. HP Ingredients is dedicated to providing science based natural health solutions that are effective in supporting the most common chronic conditions affecting our lifestyle. Heart disease, diabetes, obesity, low testosterone and low energy are conditions that have become far too common. We work closely with team of scientists from around the world to bring you LJ100® Standardized Eurycoma Longifolia Extract (22% Bioactive Eurypeptides) for men's health and sport nutrition; ParActin® – the first PPAR agonist to the market, effective for brain health, joint health, and minor pain management; Bergamonte®, a science based nutraceutical for metabolic

syndrome, cholesterol & blood glucose control, and weight management; and Delphinol, a maqui standardized extract for metabolic and blood glucose support. Most of our scientists have been awarded several worldwide patents for their innovative works.